

NATIONAL CANCER INSTITUTE

CERTIFICATES OF CONFIDENTIALITY

Background Information and
Application Procedures

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

CERTIFICATES OF CONFIDENTIALITY

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I. Background

Purpose

Certificates of Confidentiality allow researchers to avoid the involuntary release of any portion of research records containing information that could be used to identify study participants. A Certificate of Confidentiality protects the investigator and anyone else who has access to research records from being compelled to disclose identifying information in any civil, criminal, administrative, legislative or other proceedings whether federal, state, or local. *Identifying information is broadly defined as any item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of a research subject.*

Certificates can be used to promote participation in studies by assuring anonymity to participants. Certificates will be issued only when the research is of a sensitive nature, where protection is judged necessary to achieve the research objectives. For instance, a Certificate of Confidentiality may be granted if disclosure could have adverse legal consequences or damage financial standing, employability, insurability, or reputation of the participant. The Certificate will help researchers avoid involuntary disclosure which could expose subjects and their families to adverse economic, psychological, and social consequences.

History

Certificates of Confidentiality were originally authorized by a 1970 amendment to the Public Health Service Act, to protect participants in research on the use and effects of drugs. The authority to award Certificates was vested with the Secretary of the Department of Health and Human Services (DHHS). The authority was extended to research on “mental health, including research on the use and effect of alcohol and other psychoactive drugs” in 1977. In 1988, the statute was broadened such that Certificates could be sought to protect individuals participating in biomedical, behavioral, clinical, and other research, and the authority to issue Certificates was delegated to the Office of the Assistant Secretary for Health (OASH). Authority to issue Certificates for drug, alcohol, and mental health research was delegated to National Institute of Mental Health (NIMH). With the reorganization of the OASH in 1996, its Certificate authority was decentralized to the NIH Institutes, and the NIH Director further delegated this authority to certain NIH officials (Institute and Center [IC]) Directors, Deputy IC Directors, and Executive Officers). Each IC had the option of issuing its own Certificates but also had the option instead to continue to utilize NIMH, because of its experience and expertise in this area, as a Service Center. The National Cancer Institute (NCI) chose to accept authority to issue Certificates of Confidentiality for extramural research projects funded by NCI and intramural research projects with NCI Principal Investigators. NIMH continues to serve as the NIH Service Center for issuing Certificates for eligible cancer research-related projects not supported or sponsored by NCI.

Types of Projects Covered

NCI issues Certificates sparingly for single, well-defined projects rather than for groups or classes of projects. An exception is for cooperative multisite projects, in which a coordinating center or “lead” institution designated by the government Program Director can apply on behalf of all member institutions, and a single Certificate providing protection to all participating sites is issued. In this case, the application must list each participating unit, its address, and the Project Director of the participating unit on the first page of the application. The lead institution is responsible for distributing copies of the Certificate to each center or site.

Extent and Limitations of Coverage

Certificates of Confidentiality can be used to cover biomedical, behavioral, clinical, or other research, whether or not it is federally funded. However, NCI will issue Certificates only for eligible cancer-related research projects which are supported by NCI. *Researchers should take appropriate steps to safeguard research results so that individuals having access to medical records (including those who may access the records with the subject’s consent) cannot access the research results or learn the identity of research participants.*

Certificates protect against involuntary disclosure; however, information may be voluntarily released under certain circumstances. For example, research subjects may disclose or consent

to the disclosure of information (including research information) in their medical records to an insurer, and researchers may not use the Certificate to refuse disclosure under this circumstance. In addition, researchers are expected to make arrangements with local and state authorities to satisfy communicable disease reporting requirements, and subjects should be informed of this possibility in the informed consent document. Moreover, Certificates do not authorize researchers to refuse to disclose information about subjects if authorized DHHS personnel request such information for an audit or program evaluation or if such information is required by the Federal Food, Drug, and Cosmetics Act.

With the exceptions noted above, it is important to keep in mind that the authority to resist compulsory disclosure provided by a Certificate supersedes any federal, state, or local laws that require such disclosure. Although there are few court decisions involving challenges to Certificates of Confidentiality, their authority has been upheld in New York State Court of Appeals.

Period of Coverage

Certificates are issued for the specific time period set forth in the Certificate. Certificates are effective on the date of issuance or upon the commencement of the research project, if that date is later than the date of issuance. An extension of coverage of an active Certificate must be requested if the research extends beyond the expiration date of the original Certificate. However, data collected while a Certificate is in effect remains protected

after the Certificate expires and in perpetuity. It is advised that applicants select a period of coverage that may overestimate, rather than underestimate, the time required to complete the project. Requests for extensions of Certificate coverage should be made three months prior to the expiration date. They should be accompanied by a justification, documentation of the most recent Institutional Review Board (IRB) approval, and the new expected completion date for the research project.

Eligibility Criteria

Certificates are issued sparingly and are only appropriate when the research information gathered is of a sensitive nature, and protection is deemed necessary in order to achieve the research objectives while protecting the study participant's confidentiality and privacy. Studies gathering information, the disclosure of which could reasonably be expected to lead to social stigmatization or job or medical/life insurance discrimination, would qualify for a Certificate. Projects eligible for Certificates must involve the collection of sensitive information that, if disclosed, could be damaging to an individual's financial standing, reputation, insurability, or employability. Examples of cancer research projects which would be eligible include, but are not limited to, the following:

- Projects involving genetic testing for cancer predisposition. Studies involving the collection and storage of biological samples for use in subsequent research could be eligible if the scope and purposes of such research can be adequately specified.

- Studies that collect information on an individual's psychological well-being or mental health, or that include psychiatric conditions as entry criteria or confounding variables.
- Research which requires information on sexual attitudes, preferences, or practices.
- Research on human immunodeficiency virus (HIV)/AIDS.
- Studies of cancer risk related to substance abuse or research involving other illegal risk behaviors (e.g., purchase of tobacco products or alcohol by minors).
- Research in which participants may be involved in class action litigation related to exposures under study (e.g., breast implants, medications, environmental or occupational exposures).

There also may be other circumstances where personally identifiable information may be considered sensitive because of specific cultural or other factors, and protection can be granted in such cases upon appropriate justification and explanation. The above eligibility criteria apply to NCI-funded research; research in other fields may involve other kinds of personally sensitive information needing Certificate protection.

Ineligible Applications

Projects which are not research based or research related are ineligible for a Certificate of Confidentiality, as are projects which have not received IRB review and final approval. Projects collecting information, the disclosure of which is not deemed to involve significant harm or damage to the subject, are not eligible.

II. Procedures for Applying

NCI Intramural Investigators

When possible, application for a Certificate should be made in conjunction with initial or annual IRB review of research proposals. Principal Investigators should complete a brief application form (Attachment A) which will be appended to the research protocol for submission to the IRB. Protocols submitted to the Clinical IRB and the Special Studies IRB will be reviewed for human subject safety concerns and, when they receive final approval, will be forwarded to the Certificate Subcommittee as appropriate.

When applications for Certificates are out of synchrony with the IRB process, Principal Investigators may request Certificates by completing and submitting an application form (Attachment B) to the Certificate Coordinator (see page 11) , along with the research protocol and documentation of the most recent IRB review and approval (memo signed by IRB Chair).

Extramural Investigators

Investigators should complete an application form (Attachment C) with the requisite IRB review documentation and a copy of the informed consent/assent forms to be used in the study, as approved by the IRB. Applicants need not submit supplemental materials, such as the research protocol itself.

Review Procedures

Applications from NCI intramural investigators as well as from NCI-supported extramural investigators are reviewed and recommended for approval by a subcommittee (Certificate Subcommittee) of the NCI IRBs which meets on a monthly basis or as needed to review Certificate applications.

Applications recommended for approval by the Certificate Subcommittee are forwarded to the NCI Deputy Director for final approval and signature, and applicants are informed of the approval of the NCI Deputy Director by memo from the Certificate Subcommittee Chair.

Modifications to Projects and Changes in Participating Institution

Requests for modifications or amendments should be made three months prior to the needed date. These requests should be accompanied by a justification and documentation of the most recent IRB approval. An amendment to an existing Certificate should be requested when a Principal Investigator relocates to a new institution. Requests for modifications and amendments will be reviewed by the Certificate Coordinator and, in consultation with a member of the Certificate Subcommittee, recommended for approval or disapproval. If a requested modification or amendment represents a substantial change in the research scope of a project, the Certificate Subcommittee may require that a new Certificate be sought.

Agency Contacts

To obtain or submit an application or to request an extension or amendment for an existing Certificate awarded by NCI, contact:

Ms. Lynn Sayers
Certificate Coordinator
National Cancer Institute
6120 Executive Boulevard, Room 214
Rockville, Maryland 20852
Telephone: 301-402-7221
Fax: 301-402-4279
E-mail: ls67i@nih.gov

For further information about Certificates of Confidentiality, contact:

Susan M. Sieber, Ph.D.
Associate Director for Special Projects
National Cancer Institute
9000 Rockville Pike
Building 31, Room 11A48
Bethesda, Maryland 20892
Telephone: 301-496-5946
Fax: 301-496-2471
E-mail: siebers@epndce.nci.nih.gov

To obtain or submit an application or to request an extension or amendment for an existing Certificate awarded by a government agency other than NCI, contact:

Ms. Olga Boikess

National Institute of Mental Health

5600 Fishers Lane

Rockville, Maryland 20857

Telephone: 301-443-3877

III. Questions and Answers About Certificates of Confidentiality

1. What are Certificates of Confidentiality?

A Certificate of Confidentiality protects the privacy of subjects in health research projects against compulsory legal demands (e.g., court orders and subpoenas that seek the names or other identifying characteristics of research subjects) made of the investigator(s).

2. What is the purpose of the Certificate?

The Certificate was developed to protect against the involuntary release of personally identified research information of a sensitive nature sought through any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Certificates of Confidentiality were first issued by the U.S. Department of Health and Human Services (DHHS) as a means of enabling drug abuse-related research projects where, in the course of the research, the study participants may be providing legally incriminating or sensitive personal information (1). The authority was granted under the Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law No. 91-513, Section 3(a). The protection afforded by Certificates of Confidentiality thus made possible research in

substance abuse that otherwise may not have been possible. In 1974, an amendment extended coverage of the Certificates to research on “mental health, including research on the use and effect of alcohol and other psychoactive drugs.” In 1988, the law was amended yet again to broaden the use of Certificates to safeguard individuals participating in biomedical, behavioral, clinical, and other research (2). The statute, as amended, pertains to a broad spectrum of cancer-related research projects.

3. What protection does a Certificate afford?

Investigators can interpose a Certificate to avoid being required to release personally identifiable research information about individual study participants. Under this statute: “The Secretary [of the Department of Health and Human Services] may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, and on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals” (Public Health Service Act 301(d), 42 U.S.C. 241(d), as amended by Public Law No.100-607, Section 163 (November 4, 1988).

A Certificate is generally issued to a research institution for a single project (not broad groups or classes of projects).

However, for cooperative multisite projects, a coordinating center or “lead” institution can apply for, and receive, a Certificate on behalf of all member institutions. The Certificate covers the collection of sensitive research information for a defined time period; information obtained while the Certificate is in effect is protected in perpetuity.

4. What types of projects are eligible for a Certificate?

A Certificate may be appropriate when the research information is of a sensitive nature, as determined by the Certificate Subcommittee of NCI’s IRB, and the protection of a Certificate is necessary to achieve the research objectives while assuring the study participants’ confidentiality. Studies gathering information, the disclosure of which could reasonably be expected to lead to social stigmatization or job or medical/life insurance discrimination, would qualify for a Certificate. Projects eligible for Certificates must involve the collection of sensitive information which, if disclosed, could have adverse legal consequences or be damaging to an individual’s financial standing, reputation, insurability, or employability. Examples of cancer research projects which would be eligible include, but are not limited to:

- Projects involving genetic testing for cancer predisposition. In general, studies involving the collection and storage of biological samples for incompletely specified future uses, but which might include genetic studies, might be considered eligible.

- Studies collecting information on an individual's psychological well-being or mental health, or which include psychiatric conditions as entry criteria or confounding variables.
- Research which requires information on sexual attitudes, preferences, or practices.
- Research on human immunodeficiency virus (HIV)/AIDS.
- Studies of cancer risk related to substance abuse or research involving other illegal risk behaviors (e.g., purchase of tobacco products or alcohol by minors).
- Research in which participants may be involved in class action litigation related to exposures under study (e.g., breast implants, medications, environmental or occupational exposures).

These eligibility criteria apply to NCI-funded research; research in other fields may involve other kinds of personally sensitive information needing Certificate protection.

4a. What projects are NOT eligible for a Certificate?

Projects NOT eligible for a Certificate are:

- Projects that are not research-based or research-related.
- Projects that are not IRB-approved.
- Projects collecting information, the disclosure of which is not deemed to involve significant harm or damage to the subject.

5. In what situations may data protected by a Certificate be disclosed?

Data that are protected by a Certificate may be disclosed under the following circumstances:

- Voluntary disclosure of information by study participants themselves to physicians or other third parties, or authorization by study participants of release of information to insurers, employers, or other third parties.

- Voluntary reporting by the investigator of information, such as child abuse or threat of other potential violence by the study participant to the participant or others, provided such intention is specified in the informed consent document.
- Voluntary compliance by the researcher with reporting requirements of other state laws such as knowledge of a communicable disease, provided such intention is specified in the informed consent document.
- Release of information by investigators to DHHS as required for audits of research records or to the FDA as required under the federal Food, Drug, and Cosmetic Act (21U.S.C. § 301 et seq).

6. What is the researcher's responsibility to participants in a study for which a Certificate has been granted?

The investigator may not represent the issuance of a Certificate to potential participants as an endorsement of the research project by DHHS or use it in a coercive manner for recruitment of participants. The investigator must use the authority of the Certificate to resist compulsory disclosure of individually identifiable research data.

The study participants should be informed that a Certificate is in effect, and given a fair and clear explanation of the protection it affords, including the limitations and exceptions. This information may be included in the informed consent document or provided to the research participant in an additional information page. Suggested wording is as follows:

We have received a Certificate of Confidentiality from the federal government, which will help us protect your privacy. The Certificate protects against the involuntary release of information about you collected during the course of this study. The researchers involved in this project cannot be forced to disclose your identity or any information about you collected in this study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, you or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if you or your guardian requests the release of information about you in writing (through, for example, a written request to release medical records to an insurance company), the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.

Study participants may also be given a copy of the Certificate, although this is not necessary if it would impede the research. Study participants should be notified that a Certificate has expired if they are recruited to the study after the expiration date of the Certificate and an extension of the Certificate's coverage has not been granted.

7. How are Certificates of Confidentiality issued?

Under the Public Health Service Act and its amendments, the Secretary of the Department of Health and Human Services (DHHS) has the authority to grant Certificates of Confidentiality. Prior to 1996, Certificates were issued by the Office of the Assistant Secretary for Health of DHHS under a delegation of authority from the Secretary. Recently, the authority to issue Certificates has been delegated to the individual Institutes of NIH, and the National Cancer Institute has accepted this authority for NCI-funded research projects. Investigators whose research is funded by federal government entities other than NCI may apply to the National Institute of Mental Health (NIMH) for a Certificate, as described below.

Based on an application from the Principal Investigator of a specific research project, a Certificate is granted in the name of that investigator's institution for that project. When more than one institution is participating in a project, the Principal Investigator at the lead institution is responsible for

applying on behalf of all the sites, and a single Certificate is issued in which all participating sites are listed. For projects in which an investigator conducts research outside the United States but retains personally identifying research information within the United States, a Certificate may be issued for the project to the investigator at his domestic institution.

If the research scope of a project covered by a Certificate should change substantially, the Principal Investigator should request an amendment to the Certificate; however, the Certificate Subcommittee may require a new Certificate depending on the extent of the change in scope. An extension of coverage must be requested if the research extends beyond the expiration date of the original Certificate, as research information collected after the expiration of a Certificate is not protected from compelled release.

8. What is the process for Applying to NCI for a Certificate?

Extramural Investigators: Projects are not eligible for a Certificate unless they have been reviewed and approved by an IRB. Investigators should complete an application form* which solicits information about the project and the investigator, and submit it, along with IRB review documentation and a copy of the informed consent/assent forms to be used in the study, to the NCI Certificate Coordinator. Applications must be signed by the Principal Investigator and the Institutional Official.

Intramural Investigators: It is recommended that applications for a Certificate be made in conjunction with initial or annual IRB review of research protocols. When this is the case, investigators should complete an application form* which is attached to the protocol when it is submitted for IRB review. When applications are out of synchrony with the IRB process, investigators must complete and submit an application form* to the Certificate Coordinator, along with the research protocol and documentation of the most recent IRB review and approval.

*To obtain application forms, to submit a completed application, or to request an extension or amendment to an existing Certificate, the Principal Investigator should contact:

Ms. Lynn Sayers
Certificate Coordinator
National Cancer Institute
6120 Executive Boulevard, Room 214
Rockville, Maryland 20852
Telephone: 301-402-7221
Fax: 301-402-4279
E-mail: ls67i@nih.gov

For further information about NCI Certificates of Confidentiality, contact:

Susan M. Sieber, Ph.D.
Associate Director for Special Projects
National Cancer Institute

9000 Rockville Pike
 Building 31, Room 11A48
 Bethesda, Maryland 20892
 Telephone: 301-496-5946
 Fax: 301-496-2471
 E-mail: siebers@epndce.nci.nih.gov

Non-NCI Funded Investigators: Investigators interested in Certificates for research projects that are not funded or conducted by NCI may contact:

Ms. Olga Boikess
 National Institute of Mental Health
 5600 Fishers Lane
 Rockville, Maryland 20857
 Telephone: 301-443-3877

9. How are Extensions or Amendments to Existing Certificates obtained?

Requests for extensions of an expiration date for a Certificate or for other amendments should be made three months prior to the needed date. These requests should be accompanied by a justification, documentation of the most recent IRB approval, and in the case of an extension, the new expected completion date for the research project. They should be directed to the NCI Certificate Coordinator at the address above.

10. Has the legality of Certificates been challenged?

There have been court challenges to the confidentiality protections afforded by a Certificate. In 1973, the Certificate's authority was upheld in the New York Court of Appeals. The U.S. Supreme Court declined to hear the case.

11. What should an investigator do if legal action is brought to release personally identifying information protected by a Certificate?

A Certificate of Confidentiality is a legal defense against a subpoena or court order to be used by the researcher to resist disclosure. The researcher should seek legal counsel from his or her institution. The Office of General Counsel for DHHS is willing to discuss the regulations with the researcher's attorney. Should your NCI-issued Certificate be subject to court challenge, please notify:

Susan M. Sieber, Ph.D.

Associate Director for Special Projects

National Cancer Institute

9000 Rockville Pike

Building 31, Room 11A48

Bethesda, Maryland 20892

Telephone: 301-496-5946

Fax: 301-496-2471

E-mail: siebers@epndce.nci.nih.gov

References

1. Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law No. 91-513, 3(a).
2. Controlled Substances Act §502(c), 21 U.S.C. §872; Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Amendments of 1974, Public Law No. 93-282, §122; Health Omnibus Programs Extension of 1988, Public Law No. 100-607, §163.

IV. Attachment A

Application for Certificate of Confidentiality for NCI Intramural Projects in Conjunction with IRB Review

I would like to apply for a Certificate of Confidentiality for the attached proposal which is submitted to one of NCI's Institutional Review Boards for initial/annual (circle one) review and approval. In addition to the research protocol itself, which includes a copy of the informed consent/assent form to be used in the study, the following information is submitted in support of this request:

1. Name, affiliation (Institute/Division and Laboratory or Branch), and telephone number of Principal Investigator.
2. Title of project.
3. Reasons for requiring confidentiality.¹
4. Means used to protect subjects' identities.²
5. Beginning and expected end date of the project.

1. For example, "A Certificate is needed because sensitive genetic information will be generated. The Certificate will help researchers avoid involuntary disclosure which could expose subjects and their families to adverse economic, psychological, and social consequences."

2. For example, "All subjects will be assigned a coded number, and identifying information and records will be kept in locked files in the laboratory."

Note to applicant: *The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects but only protects researchers from compelled disclosure of identifying characteristics of research subjects. Researchers, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatened violence to self or others. However, if a researcher intends to make such voluntary disclosures, the consent form must clearly indicate this.*

Assurances

Personnel involved in the conduct of this research will comply with all the requirements of 45 CFR Part 46 "Protection of Human Subjects."

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS, NIH or NCI or used to coerce individuals to participate in the research project.

I will use the vested authority to protect against compelled disclosure of personally identifiable research data.

All subjects will be informed that a Certificate has been issued, and they will be provided with a description of the protection covered by the Certificate.

Subjects who enter the project after expiration of the Certificate will be informed of the termination.

I understand that if this project is not completed by the expiration date and/or an amendment is necessary, I must submit a written request for an extension of the Certificate three months prior to the expiration date. Any such request must include a justification for the extension, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Signature of Principal Investigator

V. Attachment B

Application for Certificate of Confidentiality for NCI Intramural Projects

I would like to apply for a Certificate of Confidentiality for the attached proposal which has been reviewed and approved by one of NCI's Institutional Review Boards. In addition to the research protocol itself, which includes a copy of the informed consent/assent form to be used in the study, the following information is submitted in support of this request:

1. Name, affiliation (Institute/Division and Laboratory or Branch), and telephone number of Principal Investigator.
2. Title of project.
3. Reasons for requiring confidentiality.¹
4. Means used to protect subject's identities.²
5. Beginning and expected end date of the project.
6. Documentation of IRB approval (memo signed by IRB Chair).

1. For example, "A Certificate is needed because sensitive genetic information will be generated. The Certificate will help researchers avoid involuntary disclosure which could expose subjects and their families to adverse economic, psychological, and social consequences."

2. For example, "All subjects will be assigned a coded number, and identifying information and records will be kept in locked files in the laboratory"

Note to applicant: *The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects but only protects researchers from compelled disclosure of identifying characteristics of research subjects. Researchers, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatened violence to self or others. However, if a researcher intends to make such voluntary disclosures, the consent form must clearly indicate this.*

Assurances

Personnel involved in the conduct of this research will comply with all the requirements of 45 CFR Part 46 "Protection of Human Subjects."

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS, NIH or NCI or used to coerce individuals to participate in the research project.

I will use the vested authority to protect against compelled disclosure of personally identifiable research data.

All subjects will be informed that a Certificate has been issued, and they will be provided with a description of the protection covered by the Certificate.

Subjects who enter the project after expiration of the Certificate will be informed of the termination.

I understand that if this project is not completed by the expiration date and/or an amendment is necessary, I must submit a written request for an extension of the Certificate three months prior to the expiration date. Any such request must include a justification for the extension, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Signature of Principal Investigator

VI. Attachment C

Application for Certificate of Confidentiality for NCI-Funded Extramural Projects

I would like to apply for a Certificate of Confidentiality for a project entitled _____

I am submitting the following information in support of this request (please use the numbering system shown below):

1. Source and number of the support grant.
2. Name and location of sponsoring/host institution.
3. Documentation of Institutional Review Board (IRB) approval (letter or form signed by authorized IRB representative).
4. Copy of informed consent/assent forms to be used in study, as approved by IRB.
5. Name and summary of the relevant training of the Principal Investigator. Please furnish phone number of the Principal Investigator.
6. Beginning date and expected end date of the project.
7. Concise description (e.g., 1-2 paragraphs) of the project aims and research methodology (omit "Background").
8. Reasons for requiring confidentiality.¹
9. Means used to protect subjects' identities.²

1. For example, "A Certificate is needed because sensitive genetic information will be generated. The Certificate will help researchers avoid involuntary disclosure which could expose subjects and their families to adverse economic, psychological, and social consequences."

2. For example, "All subjects will be assigned a coded number, and identifying information and records will be kept in locked files at this institution."

Note to applicant: *The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects but only protects researchers from compelled disclosure of identifying characteristics of research subjects. Researchers, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatened violence to self or others. However, if a researcher intends to make such voluntary disclosures, the consent form must clearly indicate this.*

Assurances

This institution agrees to support and defend the authority of the Certificate against legal challenges.

Personnel involved in the conduct of the research will comply with all the requirements of 45 CFR Part 46 "Protection of Human Subjects."

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS, NIH, or NCI or used to coerce individuals to participate in the research project.

I will use the vested authority to protect against compelled disclosure of personally identifiable research data.

All subjects will be informed that a Certificate has been issued, and they will be provided with a description of the protection covered by the Certificate.

Subjects who enter the project after expiration of the Certificate will be informed of the termination.

I understand that if this project is not completed by the expiration date and/or an amendment is necessary, I must submit a written request for an extension of the Certificate three months prior to the expiration date. Any such request must include a justification for the extension, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Signature of Principal Investigator

Signature of Institutional Official



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